

## **REMARKS**

### **I. INTRODUCTION**

Claim 1 has been amended. Claim 3 has been cancelled. Thus, claims 1, 2, 4-9, and 11 remain pending in the present application. No new matter has been added. In light of the above amendments and the following remarks, Applicants respectfully submit that all presently pending claims are in condition for allowance.

Claim 1 has been amended to incorporate the limitations of cancelled claim 3. Thus, Applicants respectfully request that the Examiner enter the amendments after final since it would not require a new search.

### **II. THE 35 U.S.C. § 103(a) REJECTION SHOULD BE WITHDRAWN**

Claims 1-9 and 11 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Melkent et al. (U.S. Patent No. 6,725,080) in view of Gordon (U.S. Patent No. 5,938,645).

Claim 1, as amended, recites, “[a] catheter system, comprising: a first catheter element with at least a first active localizer corresponding to a portion of the first catheter element, the first active localizer indicating a spatial position of the portion of the first catheter element; a second catheter element with at least a second active localizer corresponding to a portion of the second catheter element, the second active localizer indicating a spatial position of the portion of the second catheter element; and *a fixing device for fixing a position of at least one of the catheter elements in a surrounding vessel*, wherein the first and the second catheter element are slidably coupled, and wherein the first and the second active localizers simultaneously indicate the spatial positions of the portions of the first and second catheter elements.”

Melkent discloses an image-guided surgical navigation system (200) which tracks the position of a tool guide (125) and an anatomical reference frame (260) attached to a patient (202). (See Melkent, Abstract, Fig. 2). The tool guide comprises multiple

cannulas (127) which a surgeon can use to pass a surgical implement (i.e. tool) through to aid in a surgical procedure. (*Id.* at col. 7, ll. 22-28). The cannulas comprise a trackable marker (121) “to allow the surgeon to properly position and orient the tool guide into the anatomy for implement placement.” (*Id.* at col. 4, ll. 18-22). These tracking markers provide their relative positions to a sensor array (120). (*Id.* at col. 5, ll. 32-35).

Claim 1 has been amended to include the limitations of cancelled claim 3. Applicants respectfully submit that the Examiner has never asserted that the cited references disclose or suggest “*a fixing device for fixing a position of at least one of the catheter elements in a surrounding vessel*” as previously recited in claim 3 and now recited in claim 1. The Examiner specifically states that claims 1-3 are unpatentable over Melkent in view of Gordon. (*See*, 6/16/10 Office Action, pp. 2-3). However, in this rejection, there is never any assertion that either of Melkent or Gordon disclose or suggest a “fixing device.” In fact the term “fixing” or any other similar term does not appear in the rejection. Applicants respectfully submit that this is the case because neither Melkent nor Gordon disclose or suggest a fixing device,

Melkent is silent regarding a fixing device for fixing the cannulas (127) of the tool guide (125). In fact, the only force holding the tool guide (125) in place is either the user’s hand holding the handle (340) or a robotic arm holding the tool guide (125). (*See* Melkent, col. 7, ll. 29-37). Accordingly, Melkent fails to disclose or suggest “*a fixing device for fixing a position of at least one of the catheter elements in a surrounding vessel*,” as recited in claim 1. Furthermore, Applicants respectfully submit that Gordon fails to cure the deficiencies of Melkent.

Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness because the Examiner has not provided any assertion that the cited references disclose or suggest a fixing device. In order to establish a *prima facie* case of obviousness, the Examiner must provide a “clear articulation of the reason(s) why the claimed invention would have been obvious.” (*See*, MPEP 2142). The Examiner has not provided such an articulation for the claimed “fixing device” and therefore has not met

the burden for establishing a *prima facie* case of obviousness. In view of the Examiner's failure to "produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness." (*See, Id.*)

Applicants respectfully submit that Gordon fails to cure the deficiencies of Melkent and that Gordon, taken alone or in combination, fail to disclose or suggest "*a fixing device for fixing a position of at least one of the catheter elements in a surrounding vessel,*" as recited in claim 1. Accordingly, the rejection of claim 1 under 35 U.S.C. § 103(a) should be withdrawn. Because claims 2, and 4-6 depend on and, therefore, contain all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 7 recites, *inter alia*, "a) determining a spatial position of the first active localizer relative to the vascular system; and b) determining a spatial position of the second active localizer relative to the spatial position of the first active localizer, wherein the determining steps are performed substantially simultaneously."

Although the cannulas (127) of Melkent include a tracking marker (121), the positions of the cannulas are not determined with respect to the positions of the other cannulas. In fact, the positions of the cannulas (127) are not even determined with respect to the sensor array (120), which determines "the position of each object in detector space." (*See Melkent*, col. 5, ll. 35-36). Furthermore, Melkent fails to disclose or suggest that the tool guide (125) is placed within *a patient's vascular system*. Accordingly, Melkent fails to disclose or suggest "a) determining a spatial position of the first active localizer relative to the vascular system; and b) *determining a spatial position of the second active localizer relative to the spatial position of the first active localizer, wherein the determining steps are performed substantially simultaneously,*" as recited in claim 7.

The Examiner refers to Gordon to cure the deficiencies of Melkent. However, Gordon simply teaches a "a catheter having proximal and distal ends, designed to be

advanced through a hemostasis valve and guide catheter over a guide wire.” Applicants respectfully submit Gordon never discloses or suggests determining spatial positions of localizers with respect to each other because Gordon never discloses or suggests multiple localizers. Accordingly, Gordon fails to cure the deficiencies of Melkent and the Melkent and Gordon, taken alone or in combination, fail to disclose or suggest “a) determining a spatial position of the first active localizer relative to the vascular system; and b) *determining a spatial position of the second active localizer relative to the spatial position of the first active localizer, wherein the determining steps are performed substantially simultaneously,*” as recited in claim 7. Accordingly, the rejection of claim 7 under 35 U.S.C. § 103(a) should be withdrawn. Because claims 8, 9, and 11 depend on and, therefore, contain all of the limitations of claim 7, it is respectfully submitted that these claims are also allowable.

Claim 8 depends on claim 7 and recites “wherein the first catheter element is fixed relative to the vascular system, while the second catheter element is moved.” Thus, claim 8 is also separately allowable for the same reasons as described above for claim 1.

Furthermore, as stated in the previous response, the Examiner’s assertion that “[it]t would be *prima facie* obvious to modify Melkent with Gordon so that one could properly position the two catheter elements with respect to each other in small tortuous places such as blood vessels,” is not clear. Is it the Examiner’s position that one of the cannulas of Melkent can be replaced with the catheter of Gordon? If this is the case, then the combined teaching would merely show a catheter having one trackable marker either on Gordon’s catheter or guide wire. Or is it the position of the Examiner that the trackable marker on the catheter of Gordon that replaced one of the cannulas of Melkent includes a first marker and one of the remaining cannulas includes a second marker? In this case, the combined teaching would not include a second catheter with a second marker that is slidably coupled to the first catheter. The Examiner’s never addressed this argument in the final Office Action and the Examiner’s bald statement that it would be *prima facie* obvious does not make it so. The Examiner must provide some support for the assertion and fully explain how one of ordinary skill in the art would combine the


references to result in the claimed subject matter. The Applicants remind the Examiner that “[t]he Federal Circuit has stated that ‘rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’” (See, MPEP 2142). Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness because the Examiner has, in fact, merely provided a conclusory statement. If the Examiner is relying on personal knowledge to support the finding of what is known in the art, the Examiner must provide an affidavit or declaration setting forth specific factual statements and explanations to support the finding. (See 37 C.F.R. 1.104(d)(2)). Applicants respectfully submit that the Examiner must provide an articulated reason with some rational underpinning to support the rejection based on obviousness.

**CONCLUSION**

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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